

**Appln No. 10/800,380**  
**Amdt date October 12, 2005**  
**Reply to Office action of 7/12/2005**

### **REMARKS/ARGUMENTS**

In response to the Office Action dated 7/12/2005, claim 17 is withdrawn as result of a restriction requirement and claims 1-16 remain in the application. New claims 18-20 have been added to better define Applicant's invention. It is not the Applicant's intent to surrender any equivalents because of the amendments or arguments made herein. Reexamination and reconsideration of the application as amended are respectfully requested.

#### **Election/Restriction**

On page 2 of the Office Action, the Examiner has made a restriction requirement between claims 1-16 drawn to an apparatus and claim 17 drawn to a method. Applicant respectfully traverses the restriction, but to expedite the application, the Applicant elects to have claims 1-16 remain in the application and withdraws claim 17. In view of the examiner's restriction requirement, applicant retains the right to present claim 17 in a divisional requirement. This election is an affirmation of the provisional election made during a telephone conversation with Rodney v. Warfford on 6/02/05.

#### **Art-Based Objections**

On page 3 of the Office Action, claims 1-16 were rejected under 35 U.S.C. § 102(b) as being anticipated by Morgan, et al., USPN 838,434. The Applicant respectfully traverses the rejections and respectfully submits the original and new claims are patentable in light of the arguments below.

#### **The Morgan Reference**

The Morgan reference discloses a respirator to be worn by miners and others whose occupations are subject to the presence of dust in the surrounding atmosphere. See Col. 1 lines 10-23. Morgan's respirator is constructed to envelope a smaller portion of the face which reduces heat build up on the face. See Col 1. lines 29-51. Morgan's respirator is secured on the

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face of the wearer by means of an elastic band that passes round the back of the head. See Col. 3 lines 8-12. Morgan's respirator is also secured through the use of a mouthpiece. See Col. 2 lines 104 through Col. 3 line 7. Morgan's respirator operates with the mouth and nose of a user who is capable of normal breathing, i.e., breathing through the mouth and nose.

The Claims Are Patentable Over the Reference

The claims of the present invention describe a fitting for retrofitting to a tracheostomy tube. The fitting has an inlet portion for attachment to an outlet structure of the tracheostomy tube. The fitting also has an outlet portion for extending from the outlet structure of the tracheostomy tube so that the outlet portion is connected to the inlet portion. The outlet portion has at least one side opening. These aspects of the fitting (or of a tracheostomy tube which incorporates the features and benefits of the fitting) address the problem discussed in Applicant's specification at pages 1 and 2, namely the potential of occlusion of the single tube end opening at the outer end of an emplaced tracheostomy tube.

The focus of this invention is tracheostomy tubes. Tracheostomy tubes enable a person to breath through a surgically created opening in the trachea below the person's chin. Persons who have tracheostomy tubes emplaced in their throats rarely are able to breathe through their mouths and/or noses; their breathing occurs only via the tracheostomy tube. Therefore, Applicant contends that respirator and other devices which presume or rely upon a user's ability to breathe normally (via mouth and/or nose) are quite separate from and are non-analogous to tracheostomy tubes. Therefore, Applicant traverses the § 102 rejection based upon the Morgan patent for the reasons that the Morgan patent is non-analogous art in the context of the present claims.

Assuming arguendo that the Morgan reference properly may be relied upon by the Office, the reference does not teach nor suggest the limitations of the claims of the present invention. Specifically, the cited reference does not teach nor suggest the limitation of a fitting for a tracheostomy tube having an outlet portion with at least one side opening. The Morgan reference neither teaches nor suggests using the disclosed respirator on the outlet of a tracheostomy tube.

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Morgan discloses a respirator for miners to reduce tuberculosis and other pulmonary associated diseases. See Morgan Col. 1 lines 10-15. The use of Morgan's respirator in mining activity to filter particulate contaminated air is completely different from the use of a new outlet fitting on a tracheostomy tube to prevent an occlusion which, in turn, can cause strangulation. Morgan never taught nor suggested the respirator could be used to prevent an occlusion on a tracheostomy tube outlet.

Morgan asserts the disclosed respirator can be worn easily by securing one portion around a person's nose and another portion within the person's mouth via a mouthpiece. See Morgan Col. 2 line 97 through Col. 3 line 12. Accordingly, Morgan's respirator cannot easily be adapted for use on the outlet portion of a tracheostomy tube. Morgan's respirator would be far too heavy and cumbersome to be effective. A tracheostomy tube is secured against the person's neck and surrounding tissue. The outlet portion of the tracheostomy tube needs to be compact and light, or else the user can suffer extreme discomfort and possible tearing of the surrounding tissue. Morgan's respirator would be too heavy and cumbersome to effectively prevent an occlusion of the outlet portion of a tracheostomy tube.

The present invention discloses a fitting for the outlet end of a tracheostomy tube that is far more effective in preventing an occlusion. The present invention is light and compact and would be easily adaptable to existing tracheostomy tube outlets. The Morgan respirator requires an elastic band that passes round the back of the head and the use of a mouthpiece to properly secure the respirator, whereas the present invention can be attached to an existing tracheostomy tube by any one of a variety of means, such as a press-fit connection, a snap fit connection, or a frictional connection.

In light of the previously discussed arguments, the Morgan reference does not teach nor suggest the features of the present invention as claimed. Thus, it is submitted that independent claims 1, 5, 9, 13, 18, and 20 are patentable over the cited reference. Claims 2-4, 6-8, 10-12, 14-16, and 19 are also patentable over the cited reference because they also describe additional novel elements and features that are not described in the related art. New claims 18-20 are added

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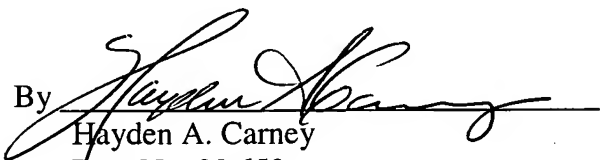
to better define Applicant's invention in light of the art of record. Fees under 37 C.F.R. § 1.16(h) for independent claims 18 and 20 are presented herewith.

**Conclusion**

As shown above, rejected claims 1-16 in the Office action of 7/12/2005 and new claims 18-20 now patentably distinguish over the Morgan reference applied in those rejections. It is submitted that this application is now in good order for allowance and such allowance is respectfully solicited.

In the event that the Office considers that the application is not now fully allowable, counsel for the Applicant requests a telephone interview before the Office begins preparation of further action herein. Grounds for a supplemental response may be discerned so that the application can be allowable without need for the issuance of a further action.

Respectfully submitted,  
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